December 3, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act
Docket No. FDA-2009-D-0008; 83 Fed. Reg. 49,935 (Oct. 3, 2018)

Dear Sir/Madam:

We are Consumer Action, Consumer Reports, Families USA, Patients for Affordable Drugs NOW, Public Citizen, and the U.S. PIRG Education Fund.

We write in support of the FDA's efforts to modernize the Section 505(q) process, specifically as it relates to Citizen Petitions filed for the primary purpose of delaying approval of generic and biosimilar medications. Generic drug competition is one of the most effective ways to reduce drug costs and ensure consumers have access to affordable medicines. Prescription drugs are of no help to consumers who cannot afford them. Robust competition among multiple interchangeable products ensures that prices for prescription medications with generic competition are a fraction of the prices charged for corresponding brand name drugs that enjoy monopoly power by blocking legitimate entry by the generics.

To illustrate, the entry of meaningful generic competition drives down drug prices by 80% on average.[1] In 2016, almost 3.9 billion generic prescriptions were dispensed in 2016, and generics account for 89% of the prescriptions dispensed, but only 26% of total drug costs in the United States.[2] In 2017, savings from generics reached a total of $265.1 billion.[3] And since generics are more affordable, patients who can be prescribed generic drugs are far less likely to abandon their prescriptions because of high costs.

We specifically have two comments on the draft guidance and the FDA's broader efforts to curb regulatory abuse meant to delay meaningful competition in the prescription drug market.

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[1] https://www.fda.gov/downloads/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm305908.PDF.
[2] https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[3] https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf.

I. Research by leading academics shows that the Citizen Petition filings are primarily used to delay competition; therefore, while we support legitimate use of these petitions, more aggressive use of the FSA's authority to summarily deny petitions that are not clearly substantiated is warranted to fulfill the intent of Congress, and would provide a large consumer benefit with little risk of harm.

Two independent studies of Citizen Petitions have shown that they rarely provide value, and are most frequently submitted by pharmaceutical companies for the purpose of delaying generic competition. A study by Professor Michael Carrier and Carl Minniti found that the FDA has denied 92% of all 505(q) petitions, and 98% of late-filed petitions.[4] The study also found that the average length of petitions has more than doubled in the past five years, while the FDA rarely grants petitions above the mean length. This has meant an increase in diverted FDA resources in addition to increased delays in processing what are determined to be meritless Petitions. The study points to anticompetitive goals as the most likely reason, and lists examples of serial petitions, late-filed petitions, and a combination of petitions with other behavior such as product-hopping and pay-for-delay settlements. Professors Robin Feldman, John Gray, and Giora Ashkenazi reached similar results in their study, which found that the Citizen Petition process has become "a key avenue for strategic behavior by pharmaceutical companies to delay entry of generic competition."[5]

Congress granted the FDA the authority to summarily dispose of a petition that is "submitted with the primary purpose of delaying" the generic application and that "the petition does not on its face raise valid scientific or regulatory issues."[6] However, the FDA has never used this power before. Congress intended that the FDA use this power to prevent the abuse of the Citizen Petition process. The legislative record is clear on this. Senator Brown stated that the impetus for the passage of Section 505(q) is to "help prevent the exploitation of the 'citizen petition' process, which delays access to lower priced medicines."[7] Likewise, Senator Kohl noted that FDA had found it "particularly troubling" that some "citizen petitions … appear designed not to raise timely concerns with respect to legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the agency to take the time to consider the arguments raised in the petition, regardless of its merits, and regardless of whether the petitioner could have made those very arguments months and months before."[8]

The fact that this power has not been used suggests there may have been some hesitancy in interpreting the statutory standard to it to enable its full use as we believe Congress intended. We would encourage the FDA to now interpret the Section 505(q)(1)(E) requirements in such a way to realize the original Congressional intent of allowing the FDA to quickly dispose of Citizen Petitions filed to game the system. As two independent studies of Citizen Petitions have shown, a greater willingness to see questionable Petitions as warranting summary disposition will have great consumer benefits with very little, if any, risk of harm.

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[4] Michael A. Carrier & Carl J. Minniti III, Citizen Petitions: Long, Late-Filed, and At-Last Denied, 66 AMERICAN UNIVERSITY LAW REVIEW 305 (2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=232319.
[5] Feldman, Robin and Gray, John and Ashkenazi, Giora, Empirical Evidence of Drug Companies Using Citizen Petitions to Hold Off Competition (February 2, 2018). UC Hastings Research Paper No. 269. Available at SSRN: https://ssrn.com/abstract=3116986.
[6] 21 U.S.C. § 355(q)(1)(E) (2012).
[7] 153 Cong. Rec. S5627 (May 7, 2007) (statement of Sen. Brown).
[8] 153 Cong. Rec. S5491 (May 7, 2007) (statement of Sen. Kohl, quoting FDA Chief Counsel Sheldon Bradshaw).

II. This Draft Guidance is an important step towards preventing regulatory abuse that delays competition, and we encourage the FDA to continue seeking ways to solve the problems that are leading to higher drug prices.

The FDA's draft guidance is an excellent step for reducing regulatory abuse and manipulation of Citizen Petitions to block competition. In a November 2017 speech before the Federal Trade Commission, FDA Commissioner Gottlieb spoke about the need to stop these abuses, and said "[o]ne of the practices that concerns me the most is when branded firms 'game' the system: taking advantage of certain rules, or exploiting loopholes in our system, to delay generic approval – and thereby extend a drug's monopoly beyond what Congress intended...So my message is this: end the shenanigans."[9]

Brand-name pharmaceutical companies have proven adept at exploiting loopholes and twisting the process at the expense of competition and consumers. We encourage the FDA to continue its efforts to make improvements to the regulatory system, and to maintain appropriate vigilance, so as to realize Commissioner Gottlieb's commitment to ensure that Americans can benefit from the cost savings that come from meaningful, robust competition, to better access affordable generic drugs.

Sincerely,

Consumer Action
Consumer Reports
Families USA
Patients for Affordable Drugs NOW
Public Citizen
U.S. PIRG Education Fund

[9] https://www.fda.gov/newsevents/speeches/ucm584195.htm.